Appendix 1

Items that shall be indicated in the Medical Device Safety Surveillance Plan

1. General Information	
1.1.	Plan number
1.2.	Plan version and date
1.3.	Summary of revision history
2. Product Basic Information	
2.1.	License number or listing number
2.2.	Product name in Chinese
2.3.	Product name in English
2.4.	Product model number
2.5.	Name of manufacturer
2.6.	Country of manufacturer
2.7.	License holder or firm that has completed the listing
2.8.	Indications (Shall be provided for indications that require surveillance)
3. Protocol Profile	
3.1.	Background of safety surveillance
3.2.	Purpose of safety surveillance
3.3.	Period of safety surveillance (Start date and end date of the period and of data collection for each stage)
3.4.	Subjects of safety surveillance or research (Please explain if there are inclusion/exclusion criteria)
3.5.	Endpoints (Definitions of related events and follow-up measures to be undertaken for events)
3.6.	Relevance between endpoints and purpose of the plan
3.7.	Implementation method (Methods and time points of data evaluation, records, analysis, and statistics, for example, description of the follow-up after product usage, please also explain the follow-up period, follow-up schedule, and their evaluation descriptions)
4. Exhibit/Appendix	
4.1.	Item and format of data collection
4.2.	Format of report for submission (Periodic safety report or safety summary report)